

Unlicensed and “Off-label” Medicines: information for patients and carers.

What is this leaflet about?

Sometimes a medicine is prescribed in a way that is not covered by its UK product licence. This does not mean that it is unsafe for use.

This leaflet explains in more detail what ‘unlicensed’ and ‘off-label’ mean and why some medicines are used in this way.

You may wish to discuss this further with your doctor or pharmacist.

What is a medicine?

Medicines are products used to prevent or treat a medical condition. They can come as tablets, capsules, liquids, injections, inhalers, creams, eye drops/ointments, suppositories, and patches.

What is a licence?

A drug company must have a product licence to advertise and sell a medicine.

The licence will state which illness or condition the medicine can be used for; the age of patients it can be given to; how much to give and how to give it.

The licence is provided by a government organisation called the MHRA (Medicines and Healthcare products Regulatory Agency).

How does a drug company get a licence?

To get a licence, the drug company must prove that the drug works for the illness or condition to be treated and is safe. They do this by trying it first in clinical trials, usually in adults aged 18-65 years. Information from the clinical trials is then given to the MHRA when the drug company applies for a licence.

The drug company cannot advertise or make any recommendations about using a medicine outside the terms of its licence.

The licensing process and clinical trials are very expensive. This means that once a drug is on the market, the company may decide not to try getting the original licence extended even if it is found to treat other symptoms.

What is meant by off-label and unlicensed use?

“Off-label” use means that the medicine is being used in a way that is different to that described in the licence. Some examples of “off-label” uses are:

- Using a medicine for a different illness to that stated in the licence. Doctors may have found that the medicine works very well for this illness or condition. This use may be supported by expert groups, but the drug manufacturer has not extended the licence.
- Using a medicine in an age group outside the licensed range (usually children or the elderly).
- Using a medicine at a higher dose than stated in the licence.

Unlicensed use means:

- A medicine has a licence in other countries, but not the UK. It has to be imported because it is not available in the UK.
- A medicine has a licence but needs to be made up to be taken as an unlicensed formulation. This is usually as a specially- prepared liquid for someone who has difficulty swallowing the licensed tablets.
- A medicine that has no licence at all. These are often medicines used for treating rare illnesses. The manufacturer may have decided that it was too expensive to carry out the clinical trials or it would be difficult to find enough patients for the clinical trials needed to get a licence.

How do I know that an “off-label” or unlicensed medicine is safe and will work?

Unlicensed and “off-label” medicines are only prescribed after careful consideration of other options available. Your doctors will have read information from medical publications supporting its use, and may have taken advice from other experts. An unlicensed or “off-label” medicine will only be used if it is the most appropriate medicine for you and your illness or condition.

How do I know whether a medicine is unlicensed or being used “off-label”?

Within hospital it is widely established practice that medicines may be used unlicensed or “off-label” if it is in your best interest. The leaflet that comes with the medicine may not say anything about how you should use it, or may say that the medicine is not suitable for being used in the way we are prescribing it. This does not mean that it cannot be used safely to treat your condition – it means that the drug company does not have a licence for using it in this way and so is not allowed to recommend this use. Your doctor or pharmacist may tell you that the medicine is not licensed or is being used outside of its license.

Where can I get information about unlicensed medicines?

Your doctor or pharmacist will be able to tell you more about the medicine.

There is also more information available on the NHS website at:

<https://www.nhs.uk/conditions/medicines-information/#>

Medicines for Children (www.medicinesforchildren.org.uk) produce leaflets that are written especially for parents and carers of children who are being prescribed unlicensed medicines.

What else do I need to know?

Sometimes it will take longer for the pharmacist to get you a supply of an unlicensed medicine. This means that you will need to also allow one or two weeks for them to get you further supplies of your medicine.

If you need any further information about your medicine, please contact the Pharmacy Medicines Information department, at the Princess Royal Hospital, Haywards Heath:

Tel: 01444 454388 (10.00am to 5.00pm, Monday to Friday)

Email: bsuh.medicines.information@nhs.net